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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/722,144	12/12/1996	MASAJI ISHIGURO	2292-038-0	3763

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/20/2001

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/722,144

Applicant(s)

ISHIGURO ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29, 32-35 and 37-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 is/are allowed.
- 6) ☒ Claim(s) 1-29, 32-34 and 37-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
.If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

The request filed on 6/27/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/722,144 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 102 and 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 69373.

The reasons were given previously; the traverses on this point presented 7/7/98 and 2/17/99 are unpersuasive. The racemate (at the 1' position; the other two positions are the same as in the claims) does indeed anticipate a specific enantiomer. In general, a claim to A is anticipated by a mixture of A + B, regardless of whether B is air, a pharmaceutical carrier, or a stereoisomer of A; the examiner knows of no case to the contrary. The claim merely requires that the claimed compound be present. It does not forbid the presence of other materials. Purity limitations are not read into claims, In re Kebrich, 96 USPQ 411. Applicants' compounds is old. If Claim 1 were patented, surely applicants would consider a mixture of Claim 1 with anything to be an infringement of the claim. Even if it didn't, with three optical centers, there are 8 possible isomers, and a genus of 8 anticipates every member, In re Petering, 133 USPQ 275. As for "actually synthesized", that is legally irrelevant. The exact compound is named on page 11. As noted previously, the exact configuration is set out on the reference. With regard to a

“correlation between cis configuration and activity”, this is not relevant for an anticipation. As for what the reference teaches, page 11 names a species; it is irrelevant whether the species was or was not prepared; the name alone is enough to put it into the public domain. Moreover, applicants’ exact (1'S, 5R, 6R) configuration is seen, as noted, at page 17, line 27, and in examples 4, 6, 7, 8, and 12.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Afonso.

The reasons were given previously; the traverse on this point is unpersuasive. As stated, the compounds are homologues. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. The narrowing of R₁ that eliminated this rejection for other claims was not done for this claim.

Applicants responded 7/7/98 that “it is known that” if the 1'R isomer has an ethyl or higher tail, it is “no longer equipped with any substantial activity.” Applicants have

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presented no evidence for this fact, nor have they presented any evidence why this would be expected to be true for the compounds with the (1'S, 5R, 6R) configuration. Moreover, applicants have presented no direct comparison to the prior art species, and hence are in no position to assert unexpected effects.

Claims 1,17-19, 32-34, 54-56 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girjavallabhan.

The reasons were given previously; the traverse of 7/7/98 on this point is unpersuasive. Compound 23 is indeed cis. This compound is a homolog, and hence the same reasoning applies. The traverse presented 2/17/99 over Girjavallabhan is not entirely understood. The relevant compound is (23); compound (14) is not. The fact that (14) was analyzed in human serum, etc, has nothing to do with the patentability of the claims over (23).

Claims 1-20, 32-34 and 37-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiguro.

The reasons were given previously; the traverse presented 7/7/98 on this point is unpersuasive. The exact same issue arises here. With regard to the traverse of 2/17/99, the same issue discussed above for Girjavallabhan is true for Ishiguro as well. The actual ones tested are the hydroxy ethyl, but as noted previously, the reference teaches hydroxy alkyl generally, rendering the C₁ - C₄ alkyls all obvious as set forth in the first action. The reference does not have to provide a problem to be solved in order to render the claims structurally obvious

Claims 1-4, 7-19, 32-34, 37-57, 60, 63, 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunagawa.

The reasons were given previously; the traverse of 7/7/98 on this point is unpersuasive. The same issues apply. Applicants ask, "Why would one skilled in the art be led to the (1'S, 5R, 6R) configuration..." Its not merely a matter of being led; the (1'S, 5R, 6R) configuration is directly taught as noted, in Ex 1-4, 33, 43-45 and 50. In the traverse presented 2/17/99, applicants argued that the claimed configuration is not preferred. This is true. But it is disclosed. A reference is available for all that it teaches, not just the best or even the preferred embodiments. In this regard, see *In re Lamberti*, 192 USPQ 278, 280; *In re Boe*, 148 USPQ 507, 510; *In re Fracalossi*, 215 USPQ 569, 570. The same is true for the fact that in Leanza, only a trans form has the 1-hydroxypropyl as preferred. Both features are clearly present in the reference, the configuration and the 1-hydroxypropyl. That they don't appear in the same molecule simply means that the reference is not an anticipation, not that it doesn't render the claims obvious.

Claims 37, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menard et al.

The reasons were given previously; the traverse presented 7/8/98 on this point is unpersuasive. The reference does indeed teach alkyl generically; a reference is not limited to what is labeled as preferred. The narrowing of R₁ that eliminated this rejection for other claims was not done for these claims.

Claims 1-29, 32, and 37-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leanza.

The reasons were given previously; the traverse presented 7/7/98 on this point is unpersuasive. This side chain is preferred as shown at Column 18, line 26 and again at Column 19, line 50, and appears in examples 83-89, and the 5R, 6R configuration is

present as noted in column 23. Applicants correct observe that both features are not shown in the same molecule, but this is tantamount to saying that the reference is not an anticipation. That is true, but this is a rejection for obviousness. With regard to the traverse presented 2/17/98, the reasoning in the Ishiguro rejection above applies here as well.

There is some ambiguity as to what the documents on the PTO-1449 submitted 7/9/1999 represent. For AY, the PTOL 1449 has "HU T065301 May 30, 1994 (Hungarian Abstract and English Translation of Abstract)." The examiner notes for the record, however, that the English presented is not a translation of the Hungarian abstract, and so the 1449 is modified accordingly. The examiner knows no Hungarian, but it is clear that there is far more in the English abstract than is present in the Hungarian text. For example, R10-R15, B', Heterocyclic', Ar, etc all appear in the English, but not in the Hungarian. The English abstract has no structures and so it is impossible to tell what these refer to. The examiner also notes that while the English material has HU T065301 and the 5/30/94 date, which also appears on the 1449, the Hungarian material has M65310 with 5/30/94 on the sheet with no abstract, and T65301 with no such date on the other sheet. Much the same is true for AW. The Hungarian Abstract (with its illegible formulae) is clearly quite different from the English abstract. Likewise for Reference AX. In this case, there is no general formula given in either the English or Hungarian documents, so the examiner cannot even determine whether these document is connected to carbapenems.

Applicants may wish to consider sending in English language equivalents of these documents.

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All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.



Mark L. Berch

Primary Examiner

Group 1620 - Art Unit 1624

December 13, 2001